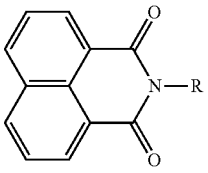
# LIPOSOMAL ELINAFIDE FORMULATIONS AND USES THEREOF

## CLAIM OF PRIORITY

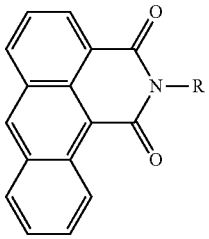
**[0001]** This application claims priority to U.S. Provisional Application No. 62/431,524 filed on Dec. 8, 2016. The entire content of the above-referenced application is incorporated by reference herein.

## BACKGROUND OF THE INVENTION

**[0002]** Naphthalimides and azonifides, classes of compounds that bind to DNA by intercalation, have been shown to possess anti-tumor activity. Both naphthalimides and azonifides are also known to interact with topoisomerases I and/or II, and such agents are known to have anti-tumor activity. Naphthalimides and azonifides are structurally related and shown below.



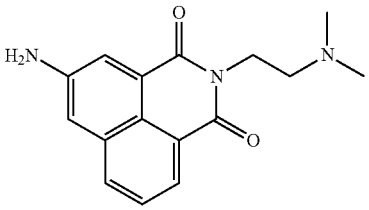
Naphthalimides



Azonifides

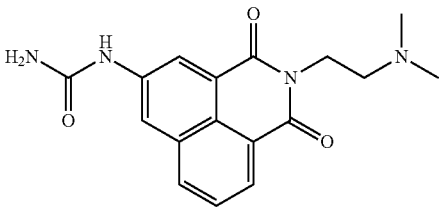
**[0003]** Despite decades of extensive research on the utility of naphthalimides and azonifides as anti-cancer agents, none is currently approved for therapeutic use, e.g., cancer therapy. There has been a number of clinical trials, but due to dose-limiting toxicity, none has ever acceded to market. For instance, a phase I study of elinafide (LU79553) demonstrated cumulative dose-limiting neuro-muscular toxicity and myelosuppression at doses at or below efficacy. Similarly, phase I studies of mitonafide, UNBS-5162, and DMP-840 showed dose limiting toxicity, including myelosuppression, irreversible CNS toxicity, QTc prolongation, neutropenia, thrombocytopenia and/or stromatitis. Recently, amonafide (AS1413) failed to enter phase III clinical trials due to high variability and dose-limiting toxicity, including myelosuppression and neutropenia.

**[0004]** The structures of these mono- and di-naphthalimides and azonifides are shown below.

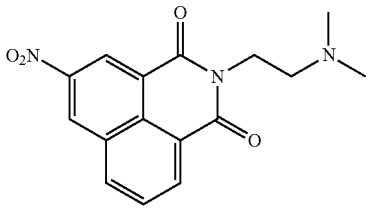


Amonafide

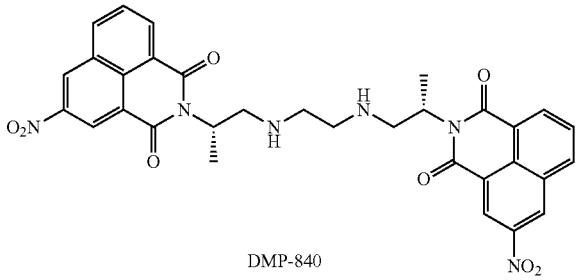
-continued



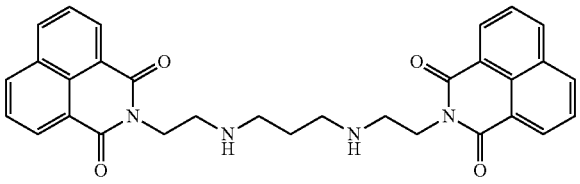
UNBS5162



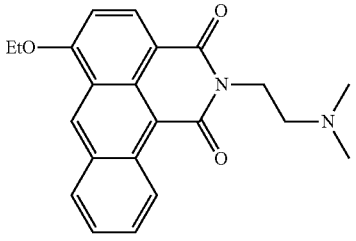
Mitonafide



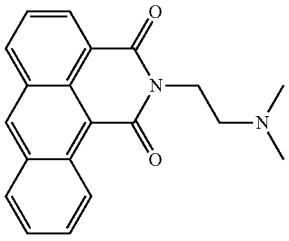
DMP-840



Elinafide



Ethonafide



Azonafide